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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,889	09/04/2003	Yung-Chi Cheng	6523-038-999	1529
20583	7590	06/30/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 06/30/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/656,889

**Applicant(s)**

CHENG ET AL.

**Examiner**

Rebecca Cook

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/4/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over CAPLUS DN 118:60030 (Kim et al). Kim (abstract) discloses that the dioxolane-cytosine is useful to treat hepatitis B virus infection (HBV). The instant claims differ over Kim in reciting the (-) enantiomer is use and dosage amounts. However, in the absence of a showing of unobviousness, no unobviousness is seen in using the (-) isomer over the (+) isomer, since a single isomer of a compound existing in more than one isomeric form is considered obvious to one of ordinary skill in the art. In re Anthony 162 USPQ 594. Furthermore, once a method of use of a compound is known it is within the skill of the artisan to determine optimum dosage amounts.

It is noted that the effective filing date of the instant application appears April 16, 1992 and the publication date of Lee is 1992. The Examiner is in the process of obtaining the exact date that the publication became available to the public. The Examiner has not been able to obtain earlier applications 07/718,806 or 07/686,617 to determine if there is support for the invention as now recited.

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Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim as applied to claims 1-4 above, and further in view of CAPLUS DN 100:203185 (Fiume et al).

Claim 5 recites that adenine arabinoside or interferon-.alpha. is further administered. However, Fiume discloses that adenine arabinoside is used to treat hepatitis B. In the absence of a showing of unexpected results, no unobviousness is seen in combining dioxolane-cytosine with adenine arabinoside, since each is taught in the art to be useful to treat hepatitis B.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,350,753 (Belleau et al). Belleau discloses (column 4, lines 1-40, column 12, lines 9-15) a compound that includes the instant compound when Z is O, including isomers, and they are useful to treat viruses. The instant claims differ over Belleau in reciting that the compound is used to treat hepatitis B virus and specific dosage amounts. However, Belleau recites amounts that include the instant dosage ranges (column 13, lines 1-4 and viruses would include the instant hepatitis B virus. In the absence of a showing of unexpected results no unobviousness is seen in the instant claims, since Belleau discloses a compound that includes the instant compound and that it is useful to treat viruses, which would include the instant hepatitis B virus.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belleau as applied to claims 1-4 above, and further in view of CAPLUS DN 100:203185 (Fiume et al).

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Claim 5 recites that adenine arabinoside or interferon-.alpha. is further administered. However, Fiume discloses that adenine arabinoside is used to treat hepatitis B. In the absence of a showing of unexpected results, no unobviousness is seen in combining dioxolane-cytosine with adenine arabinoside, since each is taught in the art to be useful to treat hepatitis B.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,350,753 (Belleau et al) in view of Varmus. Belleau discloses (column 4, lines 1-40, column 12, lines 9-15) a compound that includes the instant compound when Z is O, including isomers, and they are useful to treat viruses, especially HIV. The instant claims differ over Belleau in reciting that the compound is used to treat hepatitis B virus and specific dosage amounts. However, Belleau recites amounts that include the instant dosage ranges (column 13, lines 1-4 and viruses would include the instant hepatitis B virus. Furthermore, Varmus (page 024, column 2, paragraphs 3-4) discloses that hepatitis B and retroviruses such as HIV are temporally permuted versions of each other and have similarities in replication strategy. In the absence of a showing of unexpected results no unobviousness is seen in the instant claims, since Belleau discloses a compound that includes the instant compound and that it is useful to treat viruses, which would include the instant hepatitis B virus and Varmus discloses similarities between hepatitis B and retroviruses. Therefore, one of ordinary skill in the art would expect that a compound that interferes with the replication of HIV would also interfere with the replication of hepatitis B virus.

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Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belleau as applied to claims 1-4 above, and further in view of CAPLUS DN 100:203185 (Fiume et al).

Claim 5 recites that adenine arabinoside or interferon-.alpha. is further administered. However, Fiume discloses that adenine arabinoside is used to treat hepatitis B. In the absence of a showing of unexpected results, no unobviousness is seen in combining dioxolane-cytosine with adenine arabinoside, since each is taught in the art to be useful to treat hepatitis B.

### **IDS**

The following references were considered because they were not available in the parent file: B02-B10, B12-B28, C01-C14, C17-C25, C27-C35, C37-C50, C52-C58.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

A handwritten signature in cursive script, appearing to read 'Rebecca Cook', written in black ink.

Primary Examiner

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June 25, 2005